NIH POLICY MANUAL

1810-1 PROCEDURES FOR AVOIDING CONFLICT OF INTEREST FOR NIH SPECIAL GOVERNMENT EMPLOYEE (SGE) ADVISORY COMMITTEE MEMBERS

Issuing Office: Office of Federal Advisory Committee Policy (OFACP) 496-2123
Release Date: 04/12/99

1. Explanation of Material Transmitted: This chapter sets forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, in the use of Special Government Employees (SGEs) appointed as members of NIH advisory committees and subject to the Federal Advisory Committee Act.

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A. Purpose

This chapter sets forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, in the use of Special Government Employees (SGEs) appointed as members of NIH advisory committees and subject to the Federal Advisory Committee Act. Since Federal employees may serve as regular appointed members or ex officios of National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors, reference to conflict of interest procedures relevant to these groups are noted in this issuance.

This issuance describes procedures to ensure: (1) the appropriate collection, review, and evaluation of "Confidential Financial Disclosure Report" OGE 450 forms, and supplemental disclosure forms for prospective and current SGE advisory committee members or Federal employees serving as ex officio or regular members on advisory committees; (2) standardized methods of review of this form among Institutes and Centers; (3) appropriate verification and update of the OGE 450 forms; (4) waivers are executed, where appropriate; (5) SGE advisory committee members receive annual ethics training; and (6) confidentiality of information from these forms is maintained.

Please reference Appendix 1 for definitions of terms contained in this policy.

B. Background

The Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR Part 2635, became effective February 3, 1993 for all government employees, including SGE advisory committee members. Federal employees and SGE advisory committee members are also subject to the rules governing financial disclosure found in the Ethics in Government Act of 1978, as amended by the Ethics Reform Act of 1989, Executive Order 12674, as modified by Executive Order 12731 and 5 CFR Part 2634.

C. Policy

NIH's policy is to avoid conflicts of interest, and the appearance of such conflicts, in the selection and use of SGEs and Federal employees serving as advisory committee members and in the operation of advisory committees; to maintain adequate records regarding financial and organizational interests of such committee members; and to safeguard the confidentiality of these records.

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D. Coverage

This issuance covers Special Government Employees who are serving as appointed members of NIH National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors, and all Federal employees who are appointed as regular members or ex officios of these committees.

Since members of initial scientific and technical peer review groups are not appointed as Special Government Employees, they are <u>not</u> covered by this issuance.

E. References

- 1. Executive Order 12674 (April 12, 1989), as modified by Executive Order 12731 (October 17, 1990), "Principles of Ethical Conduct for Government Officers and Employees."
- 2. Section 208 of Title 18 of the U.S. Code.
- 3. 5 CFR Part 2635, "Standards of Ethical Conduct for Employees of the Executive Branch."
- 4. DHHS Supplemental Standards of Ethical Conduct for Employees, 5 CFR Section 5501.107.
- 5. The PHS Scientific Peer Review Regulations of Research Grant Applications and Research and Development Contract Projects, 42 CFR Part 52h.
- 6. NIH Manual 1130: Delegations of Authority, Personnel #16, "Public Financial Disclosure Reports, Confidential Financial Disclosure Reports, and Statements of Employment and Financial Interests."
- 7. NIH Manual 1130: Delegations of Authority, General Administration #9B, "Grant Conflict of Interest Waivers for Advisory Committee Members" (appointed by the Director, NIH, or Secretary, DHHS).
- 8. NIH Manual 1805: "Use of Advisors in Program & Project Review and Management."

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- 9. NIH Manual 2300-735-1: "Avoiding Conflicts of Interest".
- 10. NIH Instruction and Information Memorandum OD 90-1, "Conflict of Interest and Confidentiality Certifications for Evaluation of Grant and Cooperative Agreement Applications, Contract and Subcontract Proposals, and Active Projects", dated October 15, 1990.
- 11. NIH Manual 1743: "Keeping and Destroying Records", Item 1100-G-6.

F. Responsibilities

- 1. Institute and Center (IC) Deputy Ethics Counselors (DECs)
 - a. Ensure the avoidance of conflicts of interest, and the appearance of such conflicts, in the appointment of SGE advisory committee members.
 - b. Coordinate and manage IC financial disclosure reporting systems. Provide advice to IC staff and SGEs regarding the application of the conflict of interest guidelines and completion of financial disclosure report forms. Ensure that advisory committee members meet reporting deadlines.
 - c. Oversee, within their respective ICs, the implementation of policies and procedures set forth in this issuance and in accordance with other applicable laws, regulations, and policies.
 - d. Review, approve and sign "Confidential Financial Disclosure Report" OGE 450 forms (hereafter referred to as the OGE 450 form), and other required documentation. (See Appendices 2 and 2a)
 - Approval and signature authorities delegated to the DECs may not be redelegated. Waivers or addenda are effective upon signature of the DEC.
 - e. Review SF 278 financial disclosure forms filed by Federal employees serving as appointed members or ex officios of NIH advisory committees, for any potential conflict of interest due to committee responsibilities. Inform employees of financial interests which could create a potential conflict in relation to committee responsibilities (See Appendix 3). Provide copies of any recusals and waivers to IC Committee Management Officer.

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- 2. Ethics Counsel, NIH, Office of the General Counsel, Ethics Division (OGC/ED)
 - a. Functions as the NIH liaison to the Office of the General Counsel, Ethics Division (OGC/ED)
 - b. Provides advice, guidance, and training on conflict of interest and financial disclosure issues.
 - c. Ensures that policies and procedures affecting confidential financial disclosure systems are in compliance with OGE policies and procedures, disseminates HHS policies and procedures and OGC/ED, OGE and Department of Justice interpretations of requirements, and provides guidance and general oversight to NIH DECs.
 - d. Reviews SF 278 financial disclosure forms filed by Institute Directors who serve as DECs and as appointed members or ex officios of NIH advisory committees, for any potential conflict of interest due to committee responsibilities. Also reviews SF 278 forms filed by the Director, NIH, and the Director, NCI, who are presidential appointees.
 - e. Transmits a copy of each signed waiver and addendum to the OGE. (See Appendices 4, 4a, and 4b)
- 3. Director, Office of Federal Advisory Committee Policy
 - a. Functions as the liaison between the Office of the Secretary; the NIH Office of the General Counsel, Ethics Division; the NIH Office of General Counsel; the Department Committee Management Office; and the Institutes and Centers of NIH concerning advisory committee involvement in conflict of interest matters relating to NIH SGE advisory committee members.
 - b. Furnishes policy and guidance to NIH officials concerning procedures for collecting, reviewing, and handling conflict of interest information for NIH SGE advisory committee members.
 - c. Establishes necessary controls and procedures to ensure compliance with applicable laws, regulations and policies, and submission of required

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documents and reports.

- d. Coordinates all NIH advisory committee activities designed to avoid the occurrence of conflicts of interest or the appearance of such conflicts, in the nomination and selection of SGE advisory committee members.
- 4. Executive Secretaries (Designated Federal Officials) of NIH Advisory Committees
 - Acquire a working knowledge of pertinent statutes, regulations, policies, and procedures regarding conflict of interest and financial disclosure.
 Attend training sessions periodically on evaluation of conflict of interest situations.
 - b. Together with IC CMO, ensure that SGEs are fully aware of conflict of interest and financial disclosure requirements and, where appropriate, resolve any conflicts before service.
 - c. Review all OGE 450 forms from prospective SGE advisory committee members prior to appointment, and all Verification forms (See Appendix 5) for current members prior to each meeting. Advise the IC Deputy Ethics Counselor of potential conflicts of interest by waiver or addendum.
 - d. Review any grant or cooperative agreement applications to be considered individually at a Council or Board meeting. Determine that no member has a real or apparent conflict of interest which would preclude his or her participation in committee discussions concerning program or project concept development or concept clearance. Report any such situations to IC Director or other appropriate official(s).
 - e. Ensure that all Certifications of conflict of interest and confidentiality of information that members complete at the meeting are made part of the official meeting files.
 - f. Ensure that the procedures used to avoid conflicts of interest during the meeting are consistent with this issuance and are noted in the minutes of the meeting.
- 5. IC Committee Management Officers (IC CMOs)

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- a. Ensure that prospective SGE members of advisory committees receive letters of invitation stating that their appointment is contingent upon review and approval of their completed OGE 450 form, and that an Administrative Fact Sheet is provided which provides instructions for completing the form. Also ensure that prospective members receive appropriate personnel appointment forms, the Standards of Ethical Conduct, and other specified ethics materials.
- b. Review prospective members' OGE 450 forms to ensure that forms are completed properly. Ensure that current members receive verification forms along with copies of OGE 450 form and most recent waiver or addendum, if applicable, for updating their financial interests prior to each meeting. Perform initial conflict of interest review of completed forms.
- c. Obtain signature of acknowledgment, prior to each meeting, from Federal employees who have filed an SF 278 form, that current recusals and waivers remain in effect and of their agreement to report any changes in financial interests that may affect matters before the committee. (See Appendix 6)
- d. Ensure that all SGEs receive required annual ethics training (See Appendix 7) and maintain documentation that the material was sent, the website address for reviewing the training material was provided, or training was held.
- e. Alert the IC DEC, Executive Secretary, or other appropriate IC officials, of any potential conflict and advise on the proper procedures to handle such conflicts.
- f. In consultation with Executive Secretary, prepare general and specific waivers for SGE advisory committee members.
- g. Ensure confidentiality and security of approved OGE 450 forms, and any other information obtained or prepared in connection with the forms, in accordance with the Privacy Act, records management procedures, and NIH policy. (See NIH Manual 1743, "Keeping and Destroying Records", Item 1100-G-6.)

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6. Program Staff, Review Staff, and Grants Management Staff

Provide guidance, in their respective areas of authority, as appropriate, to assist SGE advisory committee members in avoiding participation in potential conflict of interest situations by reviewing information they submit.

In their respective areas of authority, remain alert to SGE advisory committee members' possible conflict of interest situations, and advise and assist IC CMO, Executive Secretary, and other officials with responsibilities for reviewing OGE 450 forms and Conflict of Interest and Confidentiality Certifications about these concerns.

7. Program/Project Review and Management

All NIH advisors participating in the peer review of applications and/or discussions of program or project concept development or concept clearance are required to certify at the meeting their avoidance of real and apparent conflicts of interest. Refer to NIH Manual 1805, "Use of Advisors in Program and Project Review and Management" for additional guidance.

SGE advisory committee members and NIH advisors must leave the meeting room during the individual discussion of applications with which they have an actual or potential conflict of interest. If SGE advisory committee members fail to report actual conflicts, they are subject to administrative penalties including discontinuation of service and termination of membership on committee. If SGE advisory committee members falsify information, they are subject to criminal, civil, and administrative penalties. (See Appendix 7)

8. SGE Advisory Committee Members

- a. Ensure timely appointment to advisory committee by promptly completing "Confidential Financial Disclosure Report" OGE 450 form upon receipt. Return completed OGE 450 form to IC CMO, along with other required appointment forms.
- b. Upon receipt, current members promptly complete Verification form prior to each meeting, identifying any changes in financial interests. Return completed Verification form to IC CMO.

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c. Complete certification at each meeting, acknowledging avoidance of real and apparent conflicts of interest by leaving the meeting room during the individual discussion of applications with which they may have an actual or potential conflict of interest.

G. <u>Implementation</u>

1. Overview

The Office of Government Ethics, DHHS, and NIH require that individuals who are appointed to serve as SGE advisory committee members disclose certain financial interests prior to their appointment or participation. They are also required to update this information prior to each meeting in accordance with established procedures described below, beginning with H.2.

All new SGE advisory committee members must file a "Confidential Financial Disclosure Report" OGE 450 form to determine actual or potential conflicts between the member's public responsibilities and private interests and activities. Supplemental instructions require members to report the source of any non-Federal support available for research endeavors through research or training grants, cooperative agreements, or contracts. Reporting should also be made for funds that are available to a spouse, minor child, or close professional associate for research activities. (See Appendices 2 and 2a) In all cases, a member's appointment is contingent upon approval of their completed "Confidential Financial Disclosure Report" OGE 450 form.

Authority to review and approve OGE 450 forms for SGE advisory committee members within their respective organizations has been delegated to IC Deputy Ethics Counselors (DECs). This authority may not be redelegated.

Federal employees serving as appointed members or ex officio members of National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors may already have on file a financial disclosure report (SF 278 form or OGE 450 form) with their IC or agency. This form is reviewed by the respective IC DEC for potential conflicts of interest related to their committee responsibilities. If ex officio members have not filed any form, they must complete an OGE 450 form.

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- 2. Procedures for Prospective SGE Advisory Committee Members
 - a. Upon approval of nomination, IC Committee Management Officers (IC CMOs) send a Letter of Invitation and appropriate appointment forms, including the OGE 450 form, to prospective SGE advisory committee members. An Administrative Fact Sheet which provides instructions for completing the form, and Supplemental Instructions for Reporting Non-Federal Research/Training Support on OGE 450 are also provided. (See Appendices 2 and 2a)
 - b. Prospective SGE advisory committee members complete, sign, and return the OGE 450 form, along with other appointment documents.
 - c. IC CMOs review the OGE 450 forms for completeness, returning incomplete forms to the prospective SGE or contacting the prospective SGEs for more information.
 - d. IC CMOs review the completed OGE 450 forms and, in consultation with the Executive Secretary, determine if an initial waiver is required. Prepare an initial waiver where applicable, for signature of Executive Secretary. (See Appendix 4)
 - e. IC CMOs complete tracking form, "Clearance Process to Identify and Resolve Potential Conflicts of Interest for SGE Advisory Committee Members," attaching OGE 450 form and indicating that new waiver is attached, or no new waiver is required. (See Appendix 8)
 - f. IC CMOs transmit the tracking form and OGE 450 forms with applicable waivers to IC Deputy Ethics Counselors for review and signature.
 - g. IC CMOs send a copy of each signed waiver to the Ethics Counsel, NIH, and retain the original waivers in the IC CMO office official files with the SGE advisory committee members' OGE 450 form.

NOTES:

(1) New SGE members shall be formally appointed only after approval of OGE 450 form "Confidential Financial Disclosure Report" and

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completion of other aspects of the appointment process.

- (2) A new OGE 450 form is not required for members being reappointed to the same committee, e.g., reappointments to Chair; reappointments from a partial term to a full term, provided the total service does not exceed six years. However, they are required to continue to update their form prior to each meeting.
- 3. Procedures for Current SGE Advisory Committee Members
 - a. Prior to each advisory committee meeting, IC CMOs send a "Verification of Review of Financial Interests" (See Appendix 5) to SGE advisory committee members requesting them to update their OGE 450 form and any previous waivers and addenda to reflect any changes that have occurred up to 30 working days prior to the date of the meeting for those members serving on one advisory committee, or up to 45 working days for members serving on two advisory committees at the same time.
 - Included with the verification form are copies of the SGE's most recent OGE 450 form, the most recent waiver or addendum, and instructions for completing the verification form.
 - b. SGEs review this documentation, indicate on the verification form whether there are any changes, sign the verification form, and return it to IC CMOs.
 - c. IC CMOs, in consultation with Executive Secretary, review the verification form and determine if an initial waiver, revised waiver (addendum), no waiver or disqualification is required, or if existing waiver is satisfactory. If information has changed, an "Addendum to Conflict of Interest Waivers" shall be prepared if needed to address a potential conflict. (See Appendix 4b)
 - d. IC CMOs prepare a new waiver or addendum, where applicable.
 - e. IC CMOs complete tracking form, "Clearance Process to Identify and Resolve Potential Conflicts of Interest for SGE Advisory Committee Members," attaching verification form and most recent waiver or addendum, and indicating that new waiver or addendum is attached, or that

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no new waiver or addendum is required.

- f. IC CMOs transmit the tracking form and updated forms, where required, to appropriate IC Deputy Ethics Counselor for review and signature.
- g. IC CMOs retain the original waivers and addenda with the SGE advisory committee members' OGE 450 forms, which are maintained in the IC CMO office official files, and send a copy of each signed waiver and addendum to the Ethics Counsel, NIH.
- 4. Procedures for NIH Employees Serving as Members of NIH Advisory Committees
 - a. IC CMOs notify IC DECs of those NIH employees who serve as members of NIH advisory committees, and send a copy of the committee charter to the IC DECs.
 - b. IC DECs review members' most recent SF 278 form and any recusals/disqualifications or waivers for potential conflicts of interest due to committee responsibilities. If members do not have a SF 278 form on file, they must complete an OGE 450 form, and IC CMOs are responsible for review, maintenance, and updating of forms as described in 3.a.
 - c. IC DECs return a copy of SF 278 form to the employee, along with a memo stating that recusals/disqualifications and waivers continue to apply in relation to their committee responsibilities. (See Appendix 3)
 - d. IC DECs transmit copies of SF 278 filer's current recusals/ disqualifications and waivers to IC CMOs. The SF 278 form and related documentation is maintained in the office of the IC DEC.
 - e. Prior to each meeting, IC CMOs obtain the SF 278 filer's signature of acknowledgment that current recusals and waivers remain in effect regarding the matters before the committee, and of their agreement to report any changes in their financial interests that may affect matters before the committee. IC CMOs retain the member's original acknowledgment, and sends a copy to IC DEC. (See Appendix 6)
 - f. The Ethics Counsel, NIH, reviews SF 278 forms filed by Institute Directors who serve as DECs and as appointed members or ex officios of NIH

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advisory committees, for any potential conflict of interest due to committee responsibilities. The Ethics Counsel, NIH, also reviews SF 278 forms filed by the Director, NIH, and the Director, NCI, who are presidential appointees.

- 5. Procedures for non-NIH Federal Employees Serving as Members of NIH Advisory Committees
 - a. IC CMOs request SF 278 and OGE 450 forms for non-NIH Federal employees serving on NIH advisory committees from their respective agencies, and forward to IC DECs for review. IC DECs return SF 278 forms to IC CMOs for filing. Prior to each meeting, IC CMOs obtain the SF 278 filer's signature of acknowledgment that current recusals and waivers remain in effect regarding the matters before the committee, and of their agreement to report any changes in their financial interests that may affect matters before the committee. IC CMOs retain the member's original acknowledgment. (See Appendix 6)

NOTE: The Office of Government Ethics advises that the SF 278 forms from other agencies must be marked "Confidential-Not for Public Release," and filed like the OGE 450 forms are filed. The SF 278 forms would be publicly available at the members' home agencies.

- b. If non-NIH Federal employees serving on NIH advisory committees do not have any form on file with their respective agencies, IC CMOs request members to complete OGE 450 forms and then forward these forms to IC DECs for review. IC DECs review OGE 450 forms and return original to IC CMO. IC CMOs are responsible for review, maintenance, and updating of forms prior to each meeting as described in 3.a.
- 6. Procedures for Review of OGE 450 "Confidential Financial Disclosure Report" Forms
 - a. IC CMOs review the OGE 450 and verification forms for completeness, promptly returning incomplete forms to the submitter, or making annotations based on additional information from the submitter.

In sections for which there is no information, prospective or current SGE

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advisory committee members must check "NONE" or the equivalent; blank spaces are not acceptable.

- b. Executive Secretaries review all new OGE 450 forms and verification forms submitted by prospective or current SGE advisory committee members of their committees, giving particular attention to the members' committee responsibilities in relation to employment and financial interests.
- c. IC CMO, in consultation with the Executive Secretary, shall advise the IC DEC (or designee) of potential conflicts and the need for a waiver or addendum.
- d. When an actual or apparent conflict of interest has been identified, the potential appointee may be advised of the various remedial actions available with respect to certain financial interests, so that committee membership may become possible. These remedial actions include, as appropriate:
 - (1) Issuance of a waiver under 18 U.S.C. 208(b)(3) (See 7.a. below);
 - (2) Disqualification from matters specifically involving or affecting those interests;
 - (3) Limitation of duties, voluntary resignation, or transfer to another committee; or
 - (4) Issuance of an authorization under 5 C.F.R. Part 2635 section 502. (See 8. below)

In addition, in extremely rare instances, in order for a member to serve, remedial actions may include:

- (5) Divestiture of a conflicting interest;
- (6) Resignation from a position with a non-Federal business or other entity; or

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- (7) Establishment of a qualified blind or diversified trust.
- e. The IC DEC signs the OGE 450 forms, waivers, and/or addenda as approving official.

The OGE 450 form (See Appendix 2) includes two signature blocks for review and approval. Persons delegated the authority listed above must sign as the second-level reviewing official ("Agency's Final Reviewing Official"). The first-level (or intermediate) reviewing official may be the Executive Secretary or another designated official.

- f. If an individual who has submitted an OGE 450 form is not officially appointed, the IC CMO ensures that the form is returned to the individual. The appropriate IC official documents for the record, the reasons why the individual was not officially appointed.
- 7. Procedures for Review of Waivers
 - a. SGEs: Authority 18 U.S.C. 208(b)(3)
 - (1) Criminal conflict of interest statutes preclude SGE advisory committee members from participating as Government employees in any particular matter in which, to their knowledge, they, their spouse, minor child, partner, or organization which they are seeking employment or they serve as an officer, director, trustee, general partner, or employee has a financial interest.
 - (2) A waiver is a mechanism to resolve an actual conflict of interest. For SGE advisory committee members, a waiver may be granted by the appointing authority based on the need for their services. Specifically, a waiver under 18 U.S.C. Section 208(b)(3) can be granted when the need for the members' services outweighs the potential for a conflict of interest created by the financial interest involved.
 - (3) SGE advisory committee members who would otherwise be disqualified by 18 U.S.C. 208(a) may be permitted to participate in a particular matter by means of an individual waiver issued under

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U.S.C. 208(b)(3), obtained in advance of their participation. An individual waiver may be issued if the IC Director/DEC reviews an SGE's OGE 450 form and verification form, and certifies in writing that the need for the SGE's services outweighs the potential for a conflict of interest created by the otherwise disqualifying financial interest. (See Appendix 4)

NOTE: Final approval and signature on any required waivers or addenda has been delegated to DECs and may not be redelegated.

b. Federal Employees: Authority 18 U.S.C. 208(b)(1)

All Federal employees who serve on advisory committees as either appointed members or ex officio members may participate in a particular matter by means of an individual waiver issued under U.S.C. 208(b)(1), obtained in advance of the advisory committee member's participation, if the employee's financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee. (See Appendix 4a)

NOTE: Federal employees having waivers and recusals in effect when appointed to an advisory committee will not require a 208(b)(1) waiver.

- 8. Procedures for Granting an Authorization Under 5 C.F.R Part 2635 Section 502 Regulatory Restrictions: (5 C.F.R. Part 2635 Section 502 Appearance of Conflict of Interest)
 - a. An appearance of a conflict of interest arises where an SGE is involved in a particular matter involving specific outside parties (including individuals, corporate entities, etc.) and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the SGE's impartiality in the matter.

Specific outside parties include:

(1) A member of the SGE's household, or a relative with whom the SGE has a close personal relationship;

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- (2) A person with whom the SGE has or seeks a business, contractual, or other financial relationship that involves other than a routine consumer transaction;
- (3) Any organization/person for whom the SGE's spouse, parent or dependent child is, to the SGE's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;
- (4) Any organization/person for whom the SGE has, within the last year, served as an officer, director, trustee, general partner, agency, attorney, consultant, contractor, or employee; or
- (5) An organization in which the SGE is an active participant.
- b. It is the responsibility of the appropriate IC DEC to determine whether the SGE should be authorized to participate in the matter. The IC DEC may determine that the SGE's impartiality is likely to be questioned and the SGE should not participate in the matter, or that any question of impartiality is insignificant and an authorization should be given, allowing the SGE to participate in the matter.
- c. In granting an authorization, the IC DEC must find that, in light of all relevant circumstances, the interest of the Government in the SGE's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations.

Factors to consider are as follows:

- (1) The nature of the relationship involved;
- (2) The effect that the resolution of the matter would have upon the financial interests of the person involved in the relationship;
- (3) The nature and importance of the SGE's role in the matter, including the extent to which the SGE is called upon to exercise

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discretion in the matter;

- (4) The sensitivity of the matter;
- (5) The difficulty of reassigning the matter to another SGE or other government employee; and
- (6) Adjustments that can be made in the SGE's duties that would reduce or eliminate the likelihood that a reasonable person would question the SGE's impartiality.
- d. The authorization shall be documented in writing at the discretion of the IC DEC or when requested by the SGE.
- 9. Availability of "Confidential Financial Disclosure Report" Forms (OGE 450) and Related Documents

ICs may order supplies of OGE 450 "Confidential Financial Disclosure Report" forms through the General Service Administration's (GSA) Federal Supply Service, National Stock Number 7540-01-351-9173, or download the form from the Office of Government Ethics (OGE) web site: http://www.usoge.gov/Local reproduction of form is permitted.

H. <u>Multi-Campus Institutions</u>

1. Private Institutions and Affiliates

This section applies ONLY to private institutions and affiliates.

- a. An SGE advisory committee member who is employed by a private institution may participate in the review of a grant application submitted by an affiliate of the private institution if:
 - (1) the SGE does not hold a joint appointment with that affiliate,
 - (2) the SGE does not have affiliate-wide responsibilities, and
 - (3) the SGE has a waiver to do so.

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For example, a professor at Harvard may review a grant application from Beth Israel, a Harvard affiliate, if that professor does not hold a joint appointment with Beth Israel, does not have affiliate-wide responsibilities, and has a waiver which states the following:

Additionally, I recommend that you grant [name of individual] a waiver that would allow this individual to participate in specific matters that may affect any of the affiliates of [name of institution]. I believe that such a waiver is appropriate because [name of individual] does not hold any joint appointments with the affiliates and has no affiliate-wide responsibilities.

- b. An SGE advisory committee member who holds a joint appointment at a private institution and at one of its affiliates may participate in a review of a grant application submitted by another affiliate if:
 - (1) the SGE does not hold an appointment with the affiliate that has submitted the grant application,
 - (2) the SGE does not have affiliate-wide responsibilities, and
 - (3) the SGE has a waiver to do so.

For example, a doctor at Harvard Medical School who also holds an appointment at Massachusetts General Hospital, a Harvard affiliate, may review a grant application submitted by Beth Israel if the doctor does not hold an appointment with Beth Israel, does not have affiliate-wide responsibilities, and has a wavier which states the following:

Additionally, I recommend that you grant [name of individual] a waiver that would allow this individual to participate in specific matters that may affect any other of the affiliates of [name of institution]. I believe that such a waiver is appropriate because [name of individual] does not hold any joint appointments with any other affiliate and has no affiliate-wide responsibilities.

At meetings when applications are reviewed in groups without discussion, i.e., "en bloc" actions, all members may be present and may participate. The vote of an individual member in such instances does not apply to applications from private institutions and any affiliate in which the member holds an appointment or is otherwise in conflict.

2. State Multi-Campus Institutions

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This section applies ONLY to State multi-campus institutions.

An SGE advisory committee member who is employed by one campus of a State multi-campus institution may participate in any particular matter affecting another campus of the institution if the employee's disqualifying financial interest is employment in a position with no multi-campus responsibilities.

Example 1: An SGE member of an advisory committee convened by the National Institutes of Health is a full-time professor in the School of Engineering at one campus of a State university. The SGE **may** participate in formulating the committee's recommendation to award a grant to a researcher at another campus of the same State university system.

Example 2: A member of the Board of Regents at a State university is asked to serve on an advisory committee established by the National Institutes of Health to consider applications for grants for human genome research projects. An application from another university that is part of the same State system will be reviewed by the committee. Unless he receives an individual waiver under section 208(b)(1) [for Federal employees] or (b)(3) [for SGEs], the advisory committee member **may not** participate in matters affecting the second university that is part of the State system because as a member of the Board of Regents, he has duties and responsibilities that affect the entire State educational system.

I. Annual Ethics Training Requirement

Office of Government Ethics regulations (5 C.F.R. Part 2638 Subpart G, dated April 7, 1992; amended in 1997 and published in the Federal Register on March 12, 1997) require that all Federal employees, including SGEs, who are required to file confidential financial disclosure reports (OGE 450 and SF 278) receive annual ethics training.

The Office of the General Counsel, Ethics Division, DHHS is responsible for approving the content of annual training programs and providing training information and guidance to DECs for use in developing internal training programs.

SGE advisory committee members may meet the annual training requirement by reading written materials provided by the Office of General Counsel, Ethics Division, DHHS. (See Appendix 7). The format and type of training for NIH employees that are filers with advisory committee responsibilities is determined by the IC DEC that employs the individual, e.g., videotapes, computer-based training.

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Additionally, each year as a part of the annual ethics training, NIH SGE committee members receive a copy of a notice informing committee members associated with law, public relations, lobbying, or accounting firms that they are prohibited from receiving compensation as a result of their firm representing a specific client on a particular matter which is the subject of a committee's meetings.

IC CMOs are required to maintain documentation that the material was sent to or training held for the SGE advisory committee members.

J. <u>Confidentiality</u>

Information provided on the "Confidential Financial Disclosure Report" OGE 450 form is maintained under Privacy Act System Notice OGE/GOVT-2, "Confidential Statements of Employment and Financial Interest". The Privacy Act of 1974 (5 U.S.C. §552a) gives the subject individual right of access upon request and limits disclosure to those routine uses allowed by law.

K. Records Retention and Disposal

Records pertaining to financial disclosure are maintained in locked file cabinets and are retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Item 1100-G-6, as follows:

IC Committee Management Offices are responsible for retaining original copies of all "Confidential Financial Disclosure Report" OGE 450 forms for a minimum of six years after the member's term ends, except that documents needed in an on-going investigation will be retained until no longer needed in the investigation.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of

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Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

"Confidential Financial Disclosure Report" OGE 450 forms are confidential and shall not be released to the public except pursuant to court order or as otherwise provided under the Privacy Act.

"Public Financial Disclosure Report" SF 278 forms received from other agencies must be marked "Confidential-Not for Public Release," and filed like the OGE 450 forms are filed. The SF 278 forms are publicly available at the members' home agencies.

L. Management Controls

The purpose of this chapter is to set forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, in the use of Special Government Employees (SGEs) appointed as members of NIH Federal advisory committees subject to the Federal Advisory Committee Act. It also provides conflict of interest procedures for Federal employees who may serve on NIH Federal advisory committees.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter:

The Office of Federal Advisory Committee Policy (OFACP), IC Deputy Ethics Counselors (DECs), and Ethics Counsel, NIH.

Through this manual issuance, the OFACP in the Office of the Director, NIH, is accountable for ensuring that IC CMOs have implemented appropriate management controls.

2. Frequency of Review:

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Periodic review of IC CMO files by OFACP staff. Annual ethics training is also provided. In addition, the Office of Government Ethics, at their discretion and in their time frame, may audit any or all of the ICs within NIH.

3. Method of Review:

The OFACP staff maintain appropriate oversight through reviews of IC CMO files. Problem issues identified by the reviewers are brought to the attention of the Director, OFACP, and are again reviewed for compliance within a reasonable time. Additional training is provided, as necessary, and issuance of interim policies and procedures, as required.

4. Review Reports are sent to:

Director, OFACP; Deputy Director for Management, NIH; and when appropriate, the IC DECs and Ethics Counsel, NIH.

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DEFINITIONS

1. Actual Conflict of Interest

Members of National Advisory Councils and Boards, Program Advisory Committees, Boards of Scientific Counselors, and other individuals who serve as SGEs, are prohibited by criminal statute, 18 U.S.C. 208(a), from participating personally and substantially in an official capacity in any particular matter in which, to the SGE's knowledge, the SGE or any person whose interests are imputed to the SGE has a financial interest, if the particular matter will have a direct and predictable effect on that interest. The financial interests of the following persons (and organizations) are considered imputed to an SGE: the SGE's spouse; minor child; general partner; an organization or entity for which the SGE serves as officer, director, trustee, general partner or employee; and a person (organization) with whom the SGE is negotiating for or has an arrangement concerning prospective employment.

An SGE advisory committee member serving as a reviewer on an NIH Advisory Council/Board is considered to have a conflict of interest in an application or proposal if the application or proposal is submitted by:

- (1) the SGE's spouse, minor child or general partner;
- (2) a person or organization in which the SGE serves as officer, director, trustee, general partner, employee or ongoing consultant, expert or advisor;
- (3) a person or organization with whom the SGE is negotiating for or has an arrangement concerning prospective employment;
- (4) an organization in which the SGE member has a financial interest, such as stock ownership; or

2. Appearance of a Conflict of Interest

An appearance of a conflict of interest arises where an SGE advisory committee member is involved in a particular matter involving specific outside parties (including individuals, corporate entities, etc.) and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the SGE advisory committee member's impartiality in the matter.

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A member serving as a reviewer may have an apparent conflict of interest in an application or proposal if the application or proposal is submitted by:

- (1) a person or organization, other than a prospective employer, with whom the SGE member has or seeks a business, contractual, or other financial relationship that involves other than a routine financial transaction (e.g., person or organization which gives or awards to SGE or SGE's employing institution a research or training grant or award);
- (2) a person who is a member of the SGE member's household (other than spouse or minor child), or who is a relative with whom the SGE member has a close personal relationship;
- (3) a person or organization for whom the SGE member's spouse, parent, or dependent child is, to the member's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;
- (4) any person or organization for whom the SGE member has, within the last year, served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, employee (including advisor, researcher, trainee), expert, or speaker;
- any organization, other than a political party, in which the SGE member is an active participant;
- (6) any person or organization where the SGE member is concerned that circumstances other than those specifically described above would raise a question about the member's impartiality in reviewing the application or proposal (for example, a person with whom the SGE member has a close professional relationship outside the Government).

3. **Direct and Predictable Effect**

The term "direct and predictable effect" refers to the impact an SGE advisory committee member's official duties may have on an outside financial interest. A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately. A particular matter will not have a direct effect on a financial interest, however, if the chain

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of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter will have a predictable effect if there is a real, as opposed to a speculative, possibility that the matter will affect the financial interest. It is not necessary, however, that the magnitude of the gain or loss be known and the dollar amount of the gain or loss is immaterial.

4. **Employment**

Employment includes but is not limited to employment by foreign governments or other entities, summer and part-time employment, membership on boards of organizations, service as an officer, director, or trustee, and consultant appointments, even if unremunerated.

5. Federal Advisory Committee

Any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, which is established by statute, or established or utilized by the President or any agency official for the purpose of obtaining advice or recommendations on issues, policies, or other matters which are within the scope of his or her responsibilities and are related to the programs, responsibilities or activities of the Department. Excluded from this definition is any committee composed entirely of full-time officers or employees of the Federal Government.

6. **Financial Interest**

A financial interest, broadly defined, includes any monetary interest of the SGE advisory committee member, the spouse, or minor children. Financial interest may also include the interests of a member's general partner. A financial interest includes the interests of an outside organization in which the member serves as an officer. The interests described above are imputed to the SGE advisory committee member. Such interests include, without limitation on the value, stock interests, bank accounts, mutual funds, sector funds, consulting relationships, and leaves of absence agreements. The monetary interest may be present or future (pension plans, future royalties, and patent rights).

Financial interests may also include but are not limited to royalty or licensing agreements with, and stock ownership or options in, such organizations as non-Federal research institutions, drug companies, and companies that provide services to such organizations.

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7. Particular Matter

The criminal conflict of interest statute comes into play when an SGE advisory committee member participates in a particular matter. A particular matter refers to the official action taken by the SGE advisory committee member and includes matters that involve a deliberation, decision, or action that is focused upon the interests of specific persons, or a discrete and identifiable class of persons. A particular matter does not necessarily involve formal parties and may include governmental action, such as legislation or policy-making, that is narrowly focused on the interests of a discrete and identifiable class of persons.

8. Personal and Substantial Participation

Certain criminal statutes impose restrictions on SGE advisory committee members because of the kind of participation they may have with respect to the official duty activity. Typically this is referred to as personal and substantial participation. To participate personally means to participate directly. To participate substantially means that the SGE advisory committee member's involvement is of significance to the matter.

9. Special Government Employee (SGE)

As defined by 18 U.S.C. § 202(a), an officer or employee of the Executive Branch who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 days, either on a full-time or intermittent basis. Members of NIH Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors are appointed as SGEs.

10. Waiver

A waiver is a mechanism used to resolve an actual conflict of interest. Certain criminal statutes governing the conduct of Federal employees allow the use of a waiver to avoid the terms of the statute. An SGE advisory committee member must obtain a waiver under 18 U.S.C. 208(b)(3) when "the need for the individual's services outweighs the potential for conflict of interest created by the otherwise disqualifying financial interest." (See appendix 4) All Federal employees who are advisory committee appointed members and ex officio members, regardless of whether they file a financial disclosure report OGE 450 or SF 278, must obtain a waiver under 18 U.S.C. 208(b)(1) when "the employee's financial interest in the particular matter or matters is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such

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employee." (See appendix 4a)

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SUPPLEMENTAL INSTRUCTIONS FOR REPORTING NON-FEDERAL RESEARCH/TRAINING SUPPORT ON OGE 450

In Part I - Assets and Income

Report the source of any (even if below the \$1,000 asset threshold and the \$200 income threshold indicated on the OGE 450 form) non-federal support (e.g., funds or resources) available for direct support of your research endeavors through research or training grants, cooperative agreements, or contracts. Reporting should also be made for funds that are available to a spouse, minor child, or close professional associate for research endeavors.

You should report the source of any such support that (1) you have received in the past twelve months, (2) you are currently receiving, and (3) you may have pending for review or award.

Report the identity of the organization (including the city and state) of the non-federal research/training support, the type of organization, the identity of the principle investigator, and the dates of the projected support. Note that the amount of the non-federal support need not be reported.

This information will be used by appropriate staff to determine whether this support might be perceived to constitute a real or apparent conflict of interest in the exercise of your duties as a member of an NIH advisory committee.

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Memorandum Format for SF 278 Filers

DATE:	
TO:	[Name of Employee]
FROM:	[Name] Deputy Ethics Counselor, [IC Acronym]
RE:	SF 278, Public Financial Disclosure Report
	you with a copy of your certified SF 278 form for calendar year [0000]. I have found sed upon a review of your financial report.
In the future, y	you need not report the following items:
In the future, i	t would be helpful if you could provide the following information:
•	filing your financial disclosure report in a timely fashion. If you have any questions, e to contact me at [insert telephone number].
	t any disqualifications/waivers/other restrictions continue to apply when you serve as nember of the [insert name of advisory committee].

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Sample Conflict of Interest Waiver Format for SGE Advisory Committee Members

DATE:

TO: [Name of Appointing Official or Delegatee]

[Title]

FROM: [Name of Recommending Official]

[Title]

SUBJECT: Conflict of Interest Waiver for [Name of Individual]

I am writing to request a waiver for [name of individual], a member of the [name of advisory committee], from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under Section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. The Office of the General Counsel has determined that you are the appointing official for purposes of Section 208 in accordance with Executive Order 12731 Section 401. Therefore, you have the authority to grant [name of individual] a waiver under Section 208(b)(3).

Section 208(a) prohibits Federal Executive Branch employees, including Special Government Employees, from participating personally and substantially in matters in which any of the following individuals or organizations has a financial interest: (1) the employee; (2) the employee's spouse; (3) the employee's minor child; (4) an organization in which the employee serves as an officer, director, trustee, partner, or employee; or (5) a person or organization with which the employee is negotiating for prospective employment or has an arrangement for prospective employment. Since [name of individual] is a Special Government Employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to this individual.

The member's financial interest subject to waiver are:

Organization Kind of Organization Nature of Interest

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Sample Conflict of Interest Waiver Format for SGE Advisory Committee Members

The functions of the Committee, as stated in its charter, are to [add description of committee functions and any specific functions that are pertinent]. As a member of the [name of advisory committee], [name of individual] potentially could become involved in matters that affect reported financial interests. Under Section 208, [name of individual] is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. § 208(b)(3) to grant a waiver permitting [name of individual] to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to [name of individual] that would allow this individual to participate in the matters identified below.

First, _______. [Describe the nature of the financial interest. For example, the amount of the financial interest may be included. The relationship between the financial interest and the actions that the individual may take as a committee member should also be explained, e.g., whether the financial interest if likely directly to be affected or if the relationship is more attenuated. Along this line, describe what the individual will be doing on the committee in detail and how this work will not specifically and uniquely affect the employee's financial interests. If the employee's financial interests would be specifically affected, explain the need for a specific waiver and why another individual cannot be found to perform this service.]

Second, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. [Describe the individual's expertise and why the individual's services are essential.] We believe that this individual's participation in the deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant [name of individual] a waiver that would allow this individual to participate in general matters that may directly affect [name of individual's] financial interest, but not matters specifically and uniquely affecting [name of individual's] financial interests. I believe that such a waiver is appropriate because in this case, the need for the services of [name of individual] outweighs the potential for a conflict of interest created by the financial interest involved.

DECISION:

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 Waiver granted based on my determination, made in accordance with Section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.
 Waiver denied.
[Name of Appointing Official or Delegatee]
Date

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Sample Conflict of Interest Waiver Format for Federal Employees (Appointed and Ex Officios) Serving on Advisory Committees

DATE:

TO: [Name of Appointing Official]

[Title]

FROM: [Name of Recommending Official]

[Title]

SUBJECT: Conflict of Interest Waiver for [Name of Individual]

The purpose of this memorandum is to request that you grant a waiver from the conflict of interest prohibitions of 18 U.S.C. §208(a) for [name of individual], a member of the [name of advisory committee]. Waivers under section 208 (b)(1) may be granted by the appointing official when it is determined that "the (financial) interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect" from the employee and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant [name of individual] a waiver under section 208 (b)(1).

[Name of individual] serves as [individual's title]. Section 208(a) prohibits Federal Executive Branch employees from participating personally and substantially in particular matters that have a direct and predictable effect on a financial interest of the employee, [his/her] spouse, minor child, general partner, or any organization of which the individual is an employee, general partner, officer, director, or trustee.

[Name of individual] has disclosed [his/her] potentially conflicting personal and imputed financial interests as follows:

[Describe the types of financial interests of the individual and the identity of the person whose financial interest is involved, if other than the employee, that may present a conflict of interest. This includes, but is not limited to, interests in real or personal property, stocks, stock options, bonds, job offer, and partnership interests. In addition, describe any entities for which the individual is an officer, director, trustee, general partner, or employee. Include consultancies.

Describe the dollar value of these financial interests and compare that to the value of the employee's total assets (if known or the circumstances warrant, for example, if a particular matter or a specific party is involved).]

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PROCEDURES FOR AVOIDING CONFLICT OF INTEREST FOR NIH SPECIAL GOVERNMENT EMPLOYEE (SGE) ADVISORY COMMITTEE MEMBERS

Sample Conflict of Interest Waiver Format for Federal Employees (Appointed and Ex Officios) Serving on Advisory Committees

As [individual's title], [name of individual] might participate in matters that could affect the financial interests of an entity in which [he/she] has a personal or imputed interest. Such participation could be prohibited under section 208, but a waiver granted by you, under

18 U.S.C. §208 (b)(1) would allow **[him/her]** to participate in a limited manner. This waiver would only permit **[name of individual]** to participate in matters that would affect all similarly situated entities to the same extent, and **[he/she]** would still be disqualified from participating in any particular matter that would have a unique and distinct effect on any entity in which **[he/she]** has a personal or imputed interest, in addition to having a direct and predictable effect on any such interests.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to [name of individual] that would allow [him/her] to participate in all matters that affect the above [financial interests, companies/organizations, etc.] to the same extent as they would affect all similarly situated entities.

[Describe the reasons for granting the waiver, focusing on the test, i.e., that the interest is not so substantial as to be deemed likely to affect the integrity of the services that the Government may expect from the individual. Describe the amount of the interest and why it is not substantial.]

In addition, the nature of the duties that [name of individual] performs are such that the integrity of [his/her] services are not likely to be compromised. The duties involve [describe, e.g., the distribution of formula-based grants]. [Further describe the sensitivity of the matter, the extent to which the employee exercises discretion, the need for the employee's services in the matter, and any adjustments in the duties that would reduce the likelihood that the integrity of the employee's duties would be questioned]. Since [name of individual] is recused from participating in any particular matters that uniquely and distinctly, as well as directly and predictably, affect any of the financial interests described above, the only matters in which [he/she] will participate that will affect [his/her] financial interests will be those matters that affect the interests of all entities similarly situated to the same extent. While this participation is technically covered by the current interpretation of section 208, it poses far less risk of bias or conflict of interest than participation in matters that relate specifically to a particular entity.

Accordingly, I recommend that you grant [name of individual] a waiver that would allow [him/her] to participate as [individual's title] in all matters that may affect entities in which [he/she] has a personal or imputed interest only to the same extent as they affect all similarly situated entities. I believe that such a waiver is appropriate because in this case, the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from [name of individual].

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DECISION:			
	Waiver granted based on my determination, made in accordance with section 208 (b)(1), that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee.		
	Waiver denied.		
	[Name of Appointing Official]		
	[Date]		

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PROCEDURES FOR AVOIDING CONFLICT OF INTEREST FOR NIH SPECIAL GOVERNMENT EMPLOYEE (SGE) ADVISORY COMMITTEE MEMBERS

Sample Addendum to Conflict of Interest Waivers

ADDENDUM TO CONFLICT OF INTEREST WAIVER

NAME OF MEMBER:	[Name of Individual]
ADVISORY COMMITTEE:	[Name of Advisory Committee]
DATE OF ORIGINAL WAIVER:	[Date of Waiver]
Organization Kind of Organization	Nature of Interest
All previous financial interests:	
[Name of Company/ [e.g., Drug Company	
Institution] University] Profe	essor, self]
All changes to the above and any new item	ns, please identify:
[Name of Company/ [e.g., Drug Company	or [e.g., Stock (new) or
Institution] University] Profe	essor (new or left)]
[Describe how the new financial interests in [Describe how the new	gnature] Date
	I waiver issued to this member. Based upon the description therein of the matter ttee and the new financial interest(s) identified above, this:
	ased on my determination, made in accordance with Section 208(b)(3), that the need tweighs the potential for a conflict of interest created by the financial interest
Addendum to Waiver denied.	
[Name of IC Deputy Ethics Counselor & Signature]	Date

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Sample Verification Review of Financial Interests Form

VERIFICATION OF REVIEW OF FINANCIAL INTERESTS PRIOR TO THE MEETING OF THE [Name of Committee] [Date of Meeting]

I have reviewed my current 1) OGE 450, "Confidential Financial Disclosure Report" and 2) Request Conflict of Interest Waiver, or Addendum. I find that:					
	NO INFORMATION HA	S CHANGED FROM THAT LY			
		6 CHANGED WHICH IS ndicate addition or deletion)			
<u>ORGANIZATION</u>	KIND OF ORGANIZATION	NATURE OF INTEREST			
(PI	LEASE INCLUDE UPDATED NON-FEDERA	AL RESEARCH/TRAINING SUPPORT.)			
	TATEMENT I HAVE MADE ON THIS FORM , AND CORRECT TO THE BEST OF MY				
Signature	 Date				
Signature	Date				

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PROCEDURES FOR AVOIDING CONFLICT OF INTEREST FOR NIH SPECIAL GOVERNMENT EMPLOYEE (SGE) ADVISORY COMMITTEE MEMBERS

VERIFICATION FORM FOR FEDERAL EMPLOYEES (SF 278 FILERS) SERVING ON NIH ADVISORY COMMITTEES

I understand that my recusals/disqualifications and waivers currently in effect apply to matters which are the subject of the advisory committee on which I serve.

I agree to notify the IC Committee Management Officer of any changes in my financial interests since I last filed a financial disclosure report that may be affected by matters which are the subject of the advisory committee on which I serve.

Confirmed and acknowledged:			
[Signature of Federal Employee]			
[Date]			

ETHICS RULES FOR ADVISORY COMMITTEE MEMBERS AND OTHER INDIVIDUALS APPOINTED AS SPECIAL GOVERNMENT EMPLOYEES (SGEs)

Introduction

This summary has been prepared primarily for committee members appointed to serve on Department of Health and Human Services (HHS) advisory committees as special Government employees (SGEs). The information contained in this summary also will be useful to other SGEs not serving on advisory committees. Persons new to the Government often are surprised by, or even resentful of, the complexity of the rules governing Federal employees. Ignoring these rules, however, can result in serious consequences, including public embarrassment for the individual and the Department. If you have questions on any of the topics covered in this guidance, you should consult with the Designated Federal Official responsible for your committee or the Deputy Ethics Counselor assigned to your operating or staff division.

Definition of a Special Government Employee (SGE)

An "SGE," or "special Government employee," is an officer or employee in the executive branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days. 18 U.S.C. 202(a). This status is important because the ethics rules for SGEs are somewhat less restrictive than the rules for other Federal employees and officials.

Some members of advisory committees are appointed for a multi-year term. During their term of appointment, committee members generally will not be expected to perform work for HHS in excess of 130 days during any period of 365 consecutive days. Thus, most committee members will be considered "SGEs."

Financial Disclosure Reporting Requirements

All HHS advisory committee members appointed as SGEs are required under the Ethics in Government Act, as amended by the Ethics Reform Act of 1989, and 5 C.F.R. Part 2634, to file a financial disclosure report when first appointed. Committee members also may be required to update the information on the report before each meeting throughout their term of appointment. The information reported is used to determine the matters for which a committee member must be disqualified under the criminal financial conflict of interest statute, 18 U.S.C. 208(a), and the matters for which a committee member may be granted a waiver under 18 U.S.C. 208(b). Complete reporting is essential to protect the committee member from inadvertently violating any of the criminal conflict of interest statutes, and to assure the public that the advice provided

by an HHS advisory committee is free from any real, or perceived, conflicts of interest. The information reported by committee members is confidential and may not be released except under the limited circumstances described in the Privacy Act notice provided with the report. (SGEs who serve more than 60 days in any period of 365 consecutive days and who are compensated at certain pay levels may be required to file a publicly available financial disclosure report).

Criminal Conflict of Interest Statutes

The following criminal conflict of interest statutes (18 U.S.C. 201-216) apply to SGEs:

18 U.S.C. 201. Section 201, commonly known as the "bribery and illegal gratuities" statute, prohibits Federal employees, including SGEs, from seeking, accepting, or agreeing to receive anything of value in return for being influenced in the performance of an official act.

18 U.S.C. 203. Section 203 prohibits an SGE from receiving compensation for representational services rendered by the employee or another person before HHS or another Federal agency or other specified entity (such as a court or commission) in any particular matter involving a specific party (i) in which the SGE has participated personally and substantially as a Government employee, or (ii) which is pending in the Government agency in which the SGE is serving if the SGE has served for more than 60 days during the immediately preceding 365 days.

Exempted from this rule are representations required in the proper discharge of official duties. Also exempted are representations required in the performance of work under a grant, contract or other agreement with or for the benefit of the Government.

A <u>particular matter involving specific parties</u> is a matter that is focused upon the interests of specific persons, or a discrete and identifiable class of persons. Particular matters may include, but are not limited to, reviews of grant proposals or contract applications, other funding decisions, studies or approvals of scientific studies or projects, and other actions that involve deliberation, decision, or action.

<u>Representational services</u> include communications (written or oral) and appearances made on behalf of someone else, generally with the intent to influence or persuade the Government.

An inquiry as to the status of a pending matter is not necessarily a representation, although depending upon the context of the inquiry, it could give rise to the appearance of a prohibited representation.

To avoid appearance problems, during the period in which a committee is in session, committee members are advised not to contact Department staff concerning any matters pending before the agency, or as to which the agency has an interest. Such matters would include, for example, applications for Federal funding, progress reports regarding Cooperative Research and Development Agreements (CRADAS) or clinical trials, and pending drug investigations or

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applications.

18 U.S.C. 205. Section 205 prohibits an SGE from representing a party, with or without compensation, before HHS or another Federal agency or other specified entity (such as a court or commission) in any <u>particular matter involving a specific party</u> in which the United States is a party or has a direct and substantial interest: (i) that the SGE participated in personally and substantially as a Government employee; or (ii) which is pending in the agency in which the SGE is serving, if the SGE has served for more than 60 days during the immediately preceding 365 days.

18 U.S.C. 207. Section 207, the "post-employment" statute, imposes a lifetime ban on a former SGE from representing another person or entity to HHS or another Federal agency or other specified entity (such as a court or commission) in any particular matter involving a specific party in which the former SGE participated personally and substantially while serving in the Government. In addition, for two years after terminating Federal employment, an SGE may not make such representational communications to the Government regarding specific party matters that were pending under his or her official responsibility during the last year of Government service. Moreover, "senior employees," those paid at an annual rate equivalent to level ES-5 in the Senior Executive Service, are subject to a one-year "cooling-off" period which precludes any contacts with their former agency on any matter for which official action is sought, even if the former employee had no involvement with the matter while in Government service. For SGEs, this one-year "cooling-off" period does not apply if the SGE served less than 60 days in the one-year period prior to termination of senior employee status.

18 U.S.C. 208. Section 208(a), the main <u>conflict of interest</u> statute, prohibits an SGE from participating personally and substantially in any particular matter that could affect the financial interests of the SGE, the SGE's spouse, minor child, general partner, an organization in which the SGE serves as an officer, director, trustee, general partner, or employee, or an organization with which the SGE is negotiating or with which the SGE has an arrangement for prospective employment.

Under this statute, for example, an SGE would be prohibited from reviewing a grant application submitted by a researcher from the same university in which the SGE is employed, or a contract proposal from an association for which the SGE serves as a member of the board of directors. In these instances, the SGE would be required to recuse from participation in the reviews.

Section 208 might also prohibit the SGE from participating in setting standards for grantees or contractors in general, to the extent that the SGE's university (or any organization with which the SGE is affiliated as an officer or board member) would be affected by those standards. (Under this scenario, however, a waiver could be issued to permit the SGE to participate in such general matters. Also, a regulatory waiver might apply to this situation. See discussion below.)

A <u>waiver</u> for advisory committee members may be granted under 18 U.S.C. 208(b)(3). Section 208(b)(3) authorizes issuance of a waiver to an SGE who serves on a committee subject to the Federal Advisory Committee Act if the official responsible for the individual's appointment certifies in writing that the need for the individual's services outweighs the potential for a conflict of interest created by the particular financial interest involved. The waiver granted is considered a

"general" waiver, in that it allows participation in matters that affect all institutions, or types of institutions, similarly. Even with a general waiver, however, SGEs must disqualify themselves from participation in all matters that specifically and uniquely affect their financial interests. The Designated Federal Official responsible for a committee will explain the procedures for disqualification. SGEs who do not serve on advisory committees are subject to more exacting waiver requirements in 18 U.S.C. 208(b)(1), and a Deputy Ethics Counselor should be consulted.

In addition, under regulations issued by the Office of Government Ethics, a regulatory (i.e., automatic) waiver of the disqualification requirement of 18 U.S.C. 208 is available under certain circumstances, including instances involving the following classes of financial interests:

- interests held in broadly diversified investment funds;
- publicly traded securities of \$5,000 or less;
- publicly traded securities of \$25,000 or less if the matter is a general policy matter and the total value of all investments in the affected industry sector is no more than \$50,000;
- employment in one campus of a multi-campus state university if the matter affects only another campus and the employee does not have multi-campus responsibilities.

In addition, there is an automatic exemption which allows SGEs serving on Federal advisory committees to participate in matters of general applicability where the otherwise-disqualifying financial interest arises solely from the committee member's non-Federal employment or prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class.

Standards of Ethical Conduct

The following are some of the major Standards of Ethical Conduct regulations (5 C.F.R. Part 2635) that pertain to HHS SGE advisory committee members during the term of their appointment:

1. Teaching, Speaking and Writing in a Personal Capacity (Other Than as a Government Employee)

Generally, during their term of appointment, committee members may continue to receive fees, honoraria, and other compensation for teaching, speaking and writing undertaken in their personal or non-Governmental capacities. However, there are some limitations:

1. An SGE is prohibited from receiving compensation for teaching, speaking, and writing that "relates to the employee's official duties." 5 C.F.R. 2635.807. The "relatedness" test is met for an SGE if:

- 1. the activity is undertaken as an official Government duty;
- 2. the circumstances indicate that the invitation to engage in the activity was extended to the SGE <u>primarily</u> because of the employee's position in the Government rather than the employee's expertise on the particular subject matter;
- 3. the invitation to engage in the activity or the offer of compensation for the activity was extended to the employee, directly or indirectly, by a person who has interests that may be affected substantially by the performance or nonperformance of the employee's official duties; or
- 4. the information conveyed through the activity draws substantially on ideas or official data that are confidential or not publicly-available.
- 2. Additionally, if a committee member serves for 60 days or less during a one-year period, the SGE may <u>not</u> accept compensation for teaching, speaking, and writing if the subject matter of the teaching, speaking or writing concerns a <u>particular matter</u>, involving specific parties, in which the SGE participated or is participating personally and substantially as a Government employee.

For example, an AIDS researcher has been appointed to a four-year term as a member of an advisory committee established for the purpose of surveying and recommending modification of procedures that deter the development of treatments for HIV infection and HIV-related diseases. The committee member is not expected to serve more than 60 days each year during her four-year term of appointment.

The committee member may accept compensation for an article or speech about the deterrent effect of certain procedures required for clinical investigations and trial designs even though such issues are being discussed by the advisory committee. Clinical procedures in general are not a particular matter involving specific parties. The committee member could not accept compensation for an article or speech which recounts committee deliberations that took place in a closed meeting, or which relies upon other, non-public information. In addition, the committee member could not accept compensation for an article or speech about specific collaborations in the HIV drug development process which were discussed by the committee, since the collaborations are considered a particular matter involving specific parties.

3. If a committee member serves for more than 60 days, the SGE is additionally prohibited from receiving compensation for teaching, speaking, and writing if the subject of the activity deals in significant part with any matter to which the SGE is presently assigned or was assigned during the previous one-year period.

EXCEPTIONS:

- This rule does not preclude a committee member from receiving compensation for teaching, speaking, or writing on a subject within the committee member's discipline or inherent area of expertise based on the SGE's educational background or experience. The outside activity must not be about or distinctly related to the work the SGE is providing to the Government.
- These restrictions also do <u>not</u> apply to teaching a course requiring multiple presentations that is part of the regularly established curriculum of an institution of higher education, an elementary or secondary school, or a program of education or training sponsored and funded by the Federal, State, or local government.

II. Gifts

Any gift given to a committee member because of the member's service on an HHS advisory committee would raise concerns. The Designated Federal Official responsible for the committee should be consulted should this situation arise. Gifts given to an SGE because of the SGE's position or achievements in the private (non-Government) sector generally are not problematic.

III. Charitable Fundraising

A committee member may engage in charitable fundraising in a personal capacity as long as the committee member does not personally solicit funds or other support from any person or entity known to the committee member to be a person or entity whose interests may be substantially affected by the performance or nonperformance of the committee member's Federal duties. 5 C.F.R. 2635.808. If specific questions concerning particular fundraising events or activities should arise, the Designated Federal Official responsible for the committee should be consulted.

IV. Expert Witness

A committee member cannot serve as an expert witness, in a proceeding before a United States court or agency in which the United States is a party or has a direct and substantial interest, except on behalf of the United States, <u>if</u> the committee member participated, while a Federal employee, in the particular proceeding, unless authorized by the HHS Designated Agency Ethics Official (DAEO), who can be reached at (202) 690-7258.

In addition, a committee member who was appointed by the President, serves on a commission established by statute, or has served or is expected to serve for more than 60 days in a period of 365 consecutive days, cannot serve, other than on behalf of the United States, as an expert witness, with or without compensation, in any proceeding before a United States court or agency in which the committee member's employing agency is a party or has a direct and substantial interest unless authorized by the DAEO. 5 C.F.R. 2635.805.

V. Impartiality

Although committee members are prohibited under 18 U.S.C. 208(a) from participating in matters in which they have a financial interest, there may be other circumstances in which a committee member's participation in a particular matter involving specific parties would raise a question regarding the member's impartiality in the matter. For example, a committee member asked to review a grant application submitted by the SGE's mentor, or someone with whom the SGE has a close personal or professional relationship, would raise a concern about the committee member's impartiality in the review. In such circumstances, the committee member should discuss the relationship with the Designated Federal Official responsible for the committee and a determination will be made as to whether the member should be disqualified from participation in the matter, or should be granted an "authorization" to permit the member to participate in the matter. 5 C.F.R 2635.502.

VI. Misuse of Position

Committee members are subject to a number of prohibitions intended to address the use, or appearance of use, of "public office for private gain." 5 C.F.R. Part 2635, Subpart G. These prohibitions include:

- A. Using their HHS titles or referring to their Government positions for their own private gain, the private gain of friends, relatives, or anyone with whom they are affiliated in a non-Governmental capacity (including nonprofit organizations which they serve as officers, members, employees, or in any other business relationship), or for the endorsement of any product, service, or enterprise.
- B. Using their HHS titles or Government positions to coerce or induce another person to provide any benefit to themselves or another person.
- C. Using non-public Government information in a financial transaction to further their private interests or those of another, or disclosing confidential or non-public information without authorization.
- D. Using Government property for unauthorized purposes.

Employment by, or Gifts from, Foreign Governments

There are Constitutional limitations on a committee member's employment by a foreign government, including political subdivisions of a foreign government. For SGEs, this provision has particular relevance to positions with foreign universities that are government-operated rather than private institutions. United States Constitution, art. I 9, cl. 8. There are also statutory provisions restricting acceptance of gifts from foreign governments. 5 U.S.C. 7342. Committee members should consult with the Designated Federal Official responsible for their committee for details about these restrictions.

Lobbying Activities

In their official capacities or as a group, committee members are prohibited from engaging in any activity which directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. 18 U.S.C. 1913. When authorized, committee members may appear before any individual or group for the purpose of informing or educating the public about a particular policy or legislative proposal. Committee members also may communicate to Members of Congress at the request of any Representative or Senator. Communications to Members of Congress initiated by committee members, in their official capacity as members of the committee, should be coordinated through the Office of the Assistant Secretary for Legislation.

As private citizens, committee members may express their personal views (but not the views of the committee as a whole or the opinions of HHS) to anyone. In doing so, committee members may state their affiliation with the committee, may factually state the committee's official position on the matter (to the extent that non-public information is not used), but may not take new positions and represent those views as the committee's position on the matter. Moreover, in expressing their private views, as with all other personal (non-Governmental) activities, committee members are not permitted to use Government computers, copiers, telephones, letterhead, staff resources, or other appropriated funds. All personal activities must occur "off duty time."

In addition, committee members are prohibited in their personal capacities from making representations on behalf of others, to the Government, on <u>particular matters involving specific parties</u> in which they were involved as Government employees. (See discussion above under 18 U.S.C. 203 & 205.)

Political Activities

The Hatch Act (5 U.S.C. 7321-7328) prescribes the restrictions on certain political activities of Federal employees (see chart below). Unlike the criminal statutes and most of the other ethics rules which are fully applicable to an SGE throughout the SGE's entire term of appointment, the Hatch Act restrictions apply only during the period of any day in which the SGE actually is performing Government business. For example, if an SGE attends an advisory committee meeting from 8:00 am - 1:00 pm, at 3:00 pm, the SGE could attend a political fund raiser and even solicit political contributions from the attendees.

	Permissible Activities	Prohibited Activities (while on duty)
*	May be candidates for public office in nonpartisan elections	* May not use their official authority to interfere with an election.
*	May register and vote as they choose.	* May not collect political contributions,
*	May assist in voter registration drives.	unless both individuals are members
*	May express opinions about candidates	of the same Federal labor
	and issues.	organization and the one solicited
*	May contribute money to political organizations.	is not a subordinate employee.
*	May attend political fund raising	* May not knowingly solicit or
	functions.	discourage the political activity of any
*	May attend and be active at political rallies and meetings.	person who has business before the agency.
*	May join and be an active member of a political party or club.	* May not engage in political activity while on duty.
*	May sign nominating petitions.	* May not engage in political activity in
*	May campaign for or against	any Government office.
	referendum questions, constitutional amendments, municipal ordinances.	* May not engage in political activity while wearing an official uniform.
*	May campaign for or against candidates in partisan elections.	* May not engage in political activity while using a Government vehicle.
*	May distribute campaign literature in partisan elections.	* May not solicit political contributions from the general public.
*	May hold office in political clubs or parties (except Treasurer).	* May not actively participate as a candidate for public office in a partisan election.

Α.

There are also criminal political statutes that apply at all times and prohibit coercion and intimidation regarding political activities.